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K112628
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510(k) Summary:

Nipro Set – SLIMLINE Blood Tubing Set with Transducer Protectors and Priming Set

807.92(a)(1)

Applicant: Nipro Medical Corporation
Establishment Reg.: 1056186

Contact Person: Jessica Oswald
Regulatory Affairs Specialist

SEP 28 2012

Date of summary preparation: February 22, 2012

807.92(a)(2)

Trade Name: Nipro Set – SLIMLINE Blood Tubing Set with Transducer Protectors and Priming Set
Common Name: Blood tubing line
Classification Name: set, tubing, blood, with and without anti-regurgitation valve
Regulation Number: 21 CFR 876.5820
Panel: 78
Product Code: FJK

807.92(a)(3)

Legally marketed substantial equivalent device:
K072024 - NIPRO Set - Blood Tubing Set with Transducer Protector and Priming Set.

807.92(a)(4)

Description of device:
The SLIMLINE is a disposable bloodline intended to provide extracorporeal access to the patient's blood during Hemodialysis. One device package includes 1 arterial line (A226Y), 1 venous line (V813), 1 attached but removable priming set and two pre-attached Transducer Protectors.

The SLIMLINE is packaged sterile and labeled for single use only. There is no ability to clean and reuse this device. It is restricted for sale by or on the order of a physician.

807.92(a)(5)

Indications for Use:
The NIPRO Set - SLIMLINE is a disposable bloodline intended to provide extracorporeal access to the patient's blood during Hemodialysis.

807.92(a)(6)

Comparison of technological characteristics:
The SLIMLINE is substantially equivalent to the predicate device in the following technological characteristics –

Item of Comparison	SLIMLINE Model # A226YV813	Predicate Model # A209YV803	SE determination
Physical characteristics:	Color-coded Components: drip chambers, clamps; transducer protectors, luer locks, luer lock caps, injection ports and dialyzer connections.	Same	-
	Tubing: main tubing, heparin line, saline pigtail and blood pump segment	SE	Main tubing has been shortened on the SLIMLINE to minimize priming volume and bio-hazardous waste
Intended Use:	The NIPRO Set - SLIMLINE is a disposable bloodline intended to provide extracorporeal access to the patient's blood during Hemodialysis. It is compatible with the Fresenius 2008H, 2008K/K2 and 2008T dialysis machines.	The Nipro Set - SLIMLINE is a disposable bloodline intended to provide extracorporeal access to the patient's blood during Hemodialysis. The compatibility of available configurations is the responsibility of the physician in charge.	Machine models added to the SLIMLINE indications for use. Removal of sentence "The compatibility of available configurations is the responsibility of the physician in charge"
Operational technique:	SLIMLINE will attach the arterial line to the bottom of the dialyzer and the venous to the top, with the dialysate running cross-current.	Arterial line attached to the top, venous to the bottom. Dialysate is cross current.	Blood and dialysate filtering through the dialyzer in opposite directions
	Priming set is provided pre-attached and needs to be removed and reattached before recirculation	Priming set provided in package but not pre-attached.	Priming set provided with arterial and venous lines
	Dialyzer needs to be parallel to machine module in order to prevent kinking of bloodlines	Tubing length sufficient to prevent kinking	Kinking risks mitigated
Performance	(testing detailed below 807.92.b.1)	SE	Shorter tubing length of SLIMLINE allows more blood to be processed during the same treatment time.

807.92(b)(1)

Non-clinical tests submitted:

Bench testing was conducted to verify that the device is safe and effective for its intended use. Those tests include: Package integrity, Pressure leak (positive and negative), Endurance test of pump segment at Maximum flow rate and pressures of the dialysis machine, Pump segment performance, Endurance testing of any injection port after penetrated by 18G hypodermic needle, Priming volume assessment, Tensile testing of joints and materials of all tubing segment, ability of Transducer protector to withstand leakage when subjected to pressures up to 2 times the maximum labeled pressure (Strikethrough test), Performance test of the device's clamps, Hemocompatibility test, Performance testing of tubing to resist kinking after repeated clamping, particularly in the post pump tubing segment; these tests along with their associated results and conclusions are included in this submission.

807.92(b)(2)

Substantial equivalence was proven through bench testing. No clinical testing was required or performed in support of this 510k submission.

807.92(b)(3)

Conclusions drawn from non-clinical and clinical tests:

The results of the bench testing and the comparison of technological characteristics with the predicate device demonstrate that the SLIMLINE performs equivalent to the predicate device and is safe and effective when used as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Ms. Jessica Oswald
Regulatory Affairs Specialist
Nipro Medical Corporation
3150 NW 107th Ave.
MIAMI FL 33172

SEP 28 2012

Re: K112628

Trade/Device Name: Nipro Set – SLIMLINE Blood Tubing Set with Transducer Protector and Priming Set

Regulation Number: 21 CFR§ 876.5820

Regulation Name: Hemodialysis system and accessories

Regulatory Class: II

Product Code: FJK

Dated: August 28, 2012

Received: August 29, 2012

Dear Ms. Oswald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

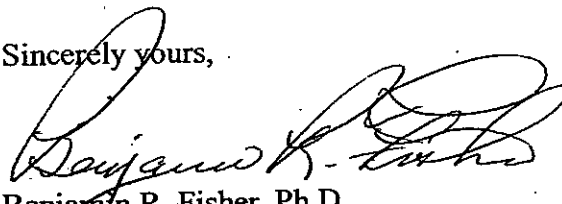
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director

Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K112628

Device Name: Nipro Set – SLIMLINE Blood Tubing Set with Transducer Protector and Priming Set

Indications for Use:

The Nipro Set - SLIMLINE is a disposable bloodline intended to provide extracorporeal access to the patient's blood during Hemodialysis.

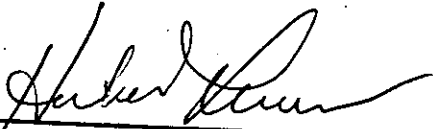
Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K112628